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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/582,059 11/20/00 JACKSON

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EXAMINER

HUANG, E

ART UNIT

PAPER NUMBER

1625

DATE MAILED:

~~10/19/01~~

12-5-01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

*\* Restarted - see Interview  
Summary. paper #9.  
B. Gray*

## Office Action Summary

Application No.

09/582,059

Applicant(s)

JACKSON ET AL.

Examiner

Evelyn Huang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 28-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other:  |

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1. Claims 1-25,28-30 are pending. Claims 26, 27 have been canceled according to the amendment filed on 8-13-2001.

### ***Claim Objections***

2. The objection over Claims 5, 6, 11-14, 17, 19 as being in improper form is obviated by the amendment.

### ***Claim Rejections - 35 USC § 112(2)***

3. The 112 second paragraph rejection is maintained for the undefined substituents of claims 2-4 set forth in paragraph 4b of the previous office action, and for the compounds 'structurally related to morphine' as set forth in paragraph 4 a, c, g of the previous office action. The compounds 'structurally related to morphine' encompass known and unknown compounds not yet discovered and is therefore indefinite, especially when the extent of structural similarity required to be considered 'related' is not defined in the claim or in the specification. The rejection is applicable to new claims 28-30.

The 112 second paragraph rejection is withdrawn for the remaining issues set forth in paragraph 4 of the previous office action

### ***Claim Rejections - 35 USC § 112(1)***

4. The 35 U.S.C. 112 first paragraph is maintained for reasons of record. The rejection is applicable to new claims 28-30.

Applicant has enclosed pages of the Sigma catalogue to show that these are commercially available opioids, which are also described in the specification. However, the rejection is directed to the opioid compounds not described in the specification but embraced by the generic claims (see paragraph 3 above and paragraphs 5, 6 below), starting materials and the process for preparation of the inventive compounds is not seen but are required. Sources are particularly pertinent especially when the structures of these 'opioid compounds' are not

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described. Absent sources, the public is offered mere language, rather than enablement. Ex parte Moersch, 104 USPQ 122.

***Claim Rejections - 35 USC § 102***

5. The 102(b) rejections over Albertson (4108857), Atsumi (3950346), Yokoyama, Atsumi (JP 49072261), Uwaydah, Maeda are maintained for reasons of record.

Applicant argues that all these prior art compounds do not have a 'charged group' as recited in the instant claims. However, 'a charged group' is not defined in the specification. These prior art compounds (corresponds to the instant (wherein  $Z=O$ ,  $R_1$  and  $R_2=H$ ) have satisfied the structural requirement of formula II of claim 7, which is subgeneric to compounds of formula I with a 'charged group'.

6. The 102(b) rejection over Hogan (WO 94/01102) is maintained for reasons of record.

Applicant argues that Hogan's compound has a net charge of zero and therefore does not satisfy the 'charged group' requirement of the instant claims. However, since the number of charges and the type of charges have not been described or defined in the specification, when given the broadest possible meaning, Hogan's zwitterionic compound would be encompassed by the instant claims.

7. The 102(b) rejection over Jackson is maintained for reasons of record. Since a compound is solely defined by the structural formula, Jackson's compound has met all the requirement of the instant formula I or II. The biological activity is an inherent property and does not further limit the claims.

***Claim Rejections - 35 USC § 103***

8. The 103(a) rejection over Jackson in view of Greene and/or Scheinmann (5977326) is maintained for reasons of record.

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Applicant argues that Jackson has taught that Compound 23 has no opioid receptor activity and is therefore teaching away from the instant. However, Compound 23 of Jackson differs from KRS 41 of instant claim 16 in having t-butyl-dimethyl-silyloxy instead of the instant hydroxy. However, Greene teaches that t-butyl-dimethyl-silyl is a well known protecting group for hydroxy (page 12; page 77). Further, in a morphine compound, Scheinmann teaches that silyl and hydrogen are optional choices for the substituents (column 2, lines 30-31). At the time of the invention, one of ordinary skill in the art would be motivated to remove the silyl protecting group to obtain the active hydroxy morphine compound to arrive at the instant invention. Further, one of ordinary skill in the art would be motivated to replace Jackson's silyl with the alternative hydrogen as taught by Scheinmann to arrive at the instant invention. Regardless of whether the protected compound has biological activity or not, to one of ordinary skill in the art, the protected derivative is prima facie obvious over the deprotected compound in the absence of unexpected results.

### *Claim Rejections - 35 USC § 112(2)*

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For the method claim, the subject and the amount of the compound are missing but are required.

### *Conclusion*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

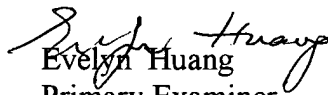
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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on 703-308-2439. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Evelyn Huang  
Primary Examiner  
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